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| 10/031,913      | 05/21/2002  | Jose Castillo Deniega | IFLOW.063NP         | 2831             |

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| EXAMINER |
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MACNEILL, ELIZABETH

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| ART UNIT | PAPER NUMBER |
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3767

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/031,913

Applicant(s)

DENIEGA ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18-28 and 73-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-28 and 73-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is in response to applicant's amendments and arguments submitted 6 October 2006.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 18, 19, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,021,044 to Sharkawy.

Sharkawy discloses a catheter having an elongated support, a porous membrane 12, non-porous membrane 11 and guidewire lumen (unnumbered). See Figures 1-3 and col. 3, lines 43-52.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 20, 21, 23, 24, 26-28 and 73-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkawy.

Sharkawy discloses the claimed invention as shown above. Sharkawy, however, does not disclose a set of ribs between the support and porous membrane in the embodiment referred above. Sharkawy discloses a set of ribs 26 in a different embodiment as shown in Figure 4. In Figure 4, it is apparent that the inner surface of the outer membrane (12) is in contact with the outer edges of the ribs (26). It is also shown that a cap (24) is attached (integral) to the distal end of the lumens. It would have been obvious to one of ordinary skill in the art to modify the invention of Sharkawy by including the ribs as disclosed by Sharkawy in a different embodiment, in order to the desirable properties of the outer material (polyethylene) used in the first embodiment of Sharkawy.

Sharkawy discloses the claimed invention as shown above. Sharkawy, however, does not disclose expressly a pore diameter of less than 0.23 microns. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to decrease the pore diameter of Sharkawy because Applicant has not disclosed that a pore diameter of less than 0.23 microns provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the pore size of Sharkawy because both would provide an efficient means of delivering fluid. Therefore, it would have been an obvious matter of design choice to modify Sharkawy to obtain the invention as specified in claims 28 and 81.

***Response to Arguments***

2. Applicant's arguments filed 6 October 2006 have been fully considered but they are not persuasive.

3. Regarding claims 18-28, Applicant has argued that Sharkawy does not teach a support with a *porous membrane* wrapped around the support, since Sharkawy teaches that the holes in the outer membrane are formed by laser drilling rather than an inherent property of the material. The Examiner does not accept the applicant's definition of a porous membrane being a material "which has a flow area defined by properties of the material" (page 5). Rather, the Examiner believes that a porous material could have pores created in it by mechanical means. Applicant's reasoning that a porous material could not have an increasing overall exit flow area when moving from a proximal to a distal end of a catheter is not convincing to the Examiner based on this definition.

4. Regarding claims 73-81, the applicant has argued that there would not be motivation to combine the embodiment of Figures 1-3 with the embodiment of Figure 4, because Sharkawy teaches that the embodiment of Figure 4 is formed in a "unitary" structure. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Examiner

believes that a unitary structure can be made of more than one material, provided the materials are connected together to form one structure. This connection is clearly shown in Figure 4. Moreover, it would be obvious to combine the two embodiments, including the feature of the previous embodiment of the inner and outer tubes being made of two separate materials, in order to retain the desirable properties of the outer material found in the first embodiment. The suggestion of using two different materials is found in Sharkawy, Col 3 lines 43-52. Furthermore, Sharkawy has chosen to use the same reference numerals (12 for the outer tube and 13 for the inner tube) in both embodiments, which further suggests that the two embodiments are constructed of the same materials.

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizabeth R. MacNeill*  
11/11/06

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*